DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Regular Clearance for the National Institute of Mental Health Data Archive (NDA), (NIMH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Andrew Hooper, National Institute of Mental Health (NIMH) Project Clearance Liaison, Science Policy and Evaluation Branch, Office of Science Policy, Planning and Communications, NIMH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Bethesda, Maryland 20892, call (301) 480-8433, or email your request, including your mailing address, to nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1)

Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The National Institute of Mental Health Data Archive (NDA), NIMH, 0925-0667, expiration date 1/31/2024, REVISION, National Institute of Mental Health (NIMH), National Institutes of Health (NIHH).

Need and Use of Information Collection: The NIMH Data Archive (NDA) is an infrastructure that allows for the submission and storage of human subjects' data from researchers conducting studies related to many scientific domains, regardless of the source of funding. The NIH and the NIMH seek to encourage use of the NDA by investigators in the field of multiple scientific research domains to achieve rapid scientific progress. In order to manage access to this data system, NIMH collects information from two categories of NDA users: (1) Investigators who seek permission to access data from the NDA for the purpose of scientific investigation, scholarship or teaching, or other forms of research and research development, via the Data Use Certification (DUC), and (2) investigators who request permission to submit data to the NDA for the purpose of scientific investigation, scholarship or teaching, or other forms of research and research development, via the Data Submission Agreement (DSA). This REVISION request is intended to facilitate NDA users' completion of the DUC and DSA by providing them with clearer guidance and updated background information.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,875.

Estimated Annualized Burden Hours

| Form Name | Type of Respondents | Number of Respondents | Number of Projects per Respondent | Average Time per Response (in hours) | Total Burden Hours |
|--|--|-----------------------|---|--------------------------------------|--------------------------|
| NDA Data Submission Agreement (DSA) | Researchers submitting data | 300 | 1 | 90/60 | 450 |
| NDA Data Use Certification (DUC) | Researchers requesting access to data | 950 | 1 | 90/60 | 1,425 |
| , , , | TOTAL | | 1,250 | | 1,875 |

Dated: March 1, 2023.

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